JUN - 9 2009

510(k) SUMMARY

Pursuant to 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR 807.92.

Submitter Information:

STAAR Surgical Company
Contact: John Santos,
Vice President Quality Assurance, Regulatory, and Clinical Affairs
1911 Walker Avenue
Monrovia, CA 91016
Phone: 626-303-7902 Fax: 626-303-2962

Company Registration Number: 2023826

Submission Correspondent:

STAAR Surgical Company
Contact: John Santos,
Vice President Quality Assurance, Regulatory, and Clinical Affairs
1911 Walker Avenue
Monrovia, CA 91016
Phone: 626-303-7902 Fax: 626-303-2962

Date Summary Prepared: January 21, 2009

Classification Name: Folders and Injectors, Intraocular Lens (IOL) (Class I) – MSS 21 CFR 886.4300

Common/Usual Name: Disposable Intraocular Lens Injector

Device Trade Name: Epiphany Injector System

The primary devices used for comparison in this summary are Rayner Surgical, Inc.'s *R-INJ-02 Single Use Disposable Injector* (K052651), Chiron Vision Corp.'s *Mport™ Foldable Lens Placement System* (K970727), Pharmacia & Upjohn's *EASYSERT Intraocular Lens Injector* (K002556), and STAAR Surgical Company's *MicroSTAAR MSI Injector System* (K940593, K954600, and K073591).

1. **Intended Use:**

   The Epiphany Injector System is a device intended to fold and insert STAAR Surgical Company aspheric three piece Collamer®, Model CQ2015A, and aspheric three piece silicone intraocular lenses, Model AQ2015A, for surgical placement in the human eye.

2. **Description:**

The single use, disposable Epiphany Injector System is a delivery system for intraocular lenses (IOLs) for surgical placement in the human eye. The two main materials used in the manufacturer of this injector system will be polycarbonate and polypropylene. All product is also supplied "STERILE."

3. **Technological Characteristics:**

The Epiphany Injector System has substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, specifications, and materials.

4. **Comparison Analysis:**

The overall design of the Epiphany Injector System is substantially equivalent to the predicate devices. See **Table 1** on the following page for a design comparison of the Epiphany Injector System and the predicate devices.

PREDICATE DEVICE COMPARISON SUMMARY TABLE						
Feature	**Epiphany Injector System**	***R-INJ-02 Single Use Disposable Injector***	***Mport™ Foldable Lens Placement System***	***EASYSERT Intraocular Lens Injector***	**MicroSTAAR MSI Injector System**	**Substantially Equivalent**
Product Description	A delivery system for intraocular lenses (IOLs)	Same	Same	Same	Same	Yes
Intended Use	See *Directions for Use*	Similar	Similar	Similar	Similar	Yes
Design	See prints	Similar	Similar	Similar	Similar	Yes
Main Materials	Polypropylene and polycarbonate	Similar	Similar	Similar	Similar	Yes
Mechanical Safety	See test results	Similar	Similar	Similar	Similar	Yes
Manufacturing	Per internal operating procedures	Similar	Similar	Similar	Similar	Yes
Operating Principle	An injector system that utilizes delivery mechanism for the insertion of an IOL.	Similar	Similar	Similar	Similar	Yes
Packaging	Labeled pouches and a tray with *Directions for Use*	Similar	Similar	Similar	Similar	Yes
Sterility	Sterile	Same	Same	Same, but different method is used	Same (MSI-P1 model)	Yes
Manufacturer	STAAR Surgical Company	Rayner Surgical, Inc.	Chiron Vision Corp.	Pharmacia & Upjohn	STAAR Surgical Company	NA

Table 1: Summary of Design Comparison

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter:

A financial certification and/or disclosure statement is not needed for this submission as no clinical studies have been undertaken in regards to the products under consideration.

(j) For submission claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990: and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (Class III Summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (Class III Certification), as described in Sec. 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the Class III Summary or Citation.

A Class III Certification and Summary is not needed for this submission as the products under consideration are Class I.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

A ***Premarket Notification Truthful and Accurate Statement*** is included on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

STAAR Surgical Company
c/o Mr. John Santos
Vice President Quality Assurance, Regulatory, and Clinical Affairs
1911 Walker Avenue
Monrovia, CA 91016

Re: K090161
Trade/Device Name: Epiphany Injector System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: June 9, 2009
Received: June 9, 2009

Dear Mr. Santos:

This letter corrects our substantially equivalent letter of June 9, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): K090161

Device Name: Epiphany Injector System

The Epiphany Injector System is a device intended to fold and insert STAAR Surgical Company aspheric three piece Collamer®, Model CQ2015A, and aspheric three piece silicone intraocular lenses, Model AQ2015A, for surgical placement in the human eye.

Prescription Use ✓ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise Hampton

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090161